

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 08-350-WO-US)

In application of)
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Lorensten, et al.) Examiner: Sheridan Swope
)
Serial No. 10/553,869)
) Group Art Unit: 1652
Filed: October 21, 2005)
)
For: Cleavage of Fusion Protein) Confirmation No.: 1881
 Using Granzyme B Protease)

APPLICANTS' REPLY BRIEF

Applicants respectfully submit this short paper to emphasize that none of the references cited by the examiner in the rejection of independent claims 1 and 40 teach the production of a polypeptide in authentic form as presently recited in each of the claims. Indeed, there is no dispute between Applicants and the Examiner on this point:

- Harris does not teach the production of a polypeptide in authentic form (*see* Applicants' Appeal Brief at p. 8; Examiner's Answer, p. 20, ¶(K) Reply (ii));
- Azad does not teach the production of a polypeptide of interest in authentic form (*see* Applicants' Appeal Brief, p. 8-9; Examiner's Answer, p. 18, ¶(H) Reply);
- Casciola-Rosen does not teach the production of a polypeptide of interest in authentic form (*see* Applicants' Appeal Brief, p. 8-9; Examiner's Answer, p. 20, ¶(L) Reply).

As discussed in Applicants' Appeal Brief, the failure of asserted references to teach or suggest each and every feature of instant claims is fatal to an obviousness rejection under 35 U.S.C. § 103. *See* Applicants' Appeal Brief, pp. 5-6; *citing Honeywell Int'l Inc. v. United States*, 609 F.3d 1292, 95 U.S.P.Q.2d 1193 (Fed. Cir. 2010); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); *In re Wada and Murphy*, Appeal 2007-3733; and MPEP § 2143.03.

Moreover, the asserted combination of references to create the missing element of the claims is completely unsupported by any factual underpinning. For instance, the Examiner recites the rationales supporting obviousness rejections (72 Fed. Reg. 57526, 57529), and attempts to apply rationales (a), (c), (g) and (e) specifically. *See* Examiner's Answer, pp. 18-19. Throughout the Examiner's Answer, however, the Examiner fails to apply the rationales with any evidence that factually supports that the suggested *combination* of references would create the missing element. The Examiner concludes that one of skill in art would "easily recognize" the Examiner's asserted combination of references. *Id.*, p. 21, ¶(M) Reply. The Examiner, however, fails to identify any evidence that one of skill in the art would "easily recognize" anything based upon the teaching in the references, none of which by themselves recite the missing claim element.

Because a critical element is missing from all of the references, the Examiner's conclusion involves more than simply combining known elements, it is the *invention of a whole new element*. Therefore, the various rationales for obviousness that the Examiner identifies do not apply in this situation. While the Examiner has the benefit of hindsight, the Applicants had no such advantage in the conception of their invention.

Applicants have invented a novel, non-obvious and useful method for producing polypeptides using a Granzyme B enzyme. Accordingly, Applicants respectfully request the all of the rejections be reversed.

Respectfully submitted,

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